

### **REMARKS**

Applicants have carefully reviewed and considered the Final Office Action mailed on February 22, 2008 and the references cited therewith. Reconsideration and withdrawal of the rejections of the claims of the above-identified application in view of the amendments and remarks presented herein is respectfully requested.

Claims 1, and 3-9 are amended, and claims 2 and 23-26 are canceled; as a result, claims 1, 3-14 and 22 are now pending in this application.

Claims 23-26 are canceled because the Examiner made the Restriction Requirement final in the previous Office Action (mailed May 30, 2007) and examined only claims 1-14 and 22. Applicants retain the right to file any or all of the claims in other applications including continuation or divisional applications.

Support for the amendment to claim 1 is found in originally filed claim 2. The amendments to claims 3-9 are made to further clarify Applicants' claims. Applicants believe that no new matter is added by the amendments to the claims and respectfully request their entry by the Examiner.

#### **I. The Rejection of the Claims under 35 U.S.C. §102(b) and 103(a)**

Claims 1-14 and 22 were rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative under 35 U.S.C. § 103(a) as obvious over, Wu (U.S. Pub. No. 2002/0044998). This rejection, as it applies to claims 1, 3-14 and 22, is respectfully traversed. Insofar as the rejection applies to claim 2, this rejection is mooted by Applicants' cancellation of claim 2.

Applicants' claim 1 is directed to a method for preparing an enriched bioactive protein product from salt whey wherein fat is removed from salt whey to provide clarified salt whey, and salt is removed from the clarified salt whey to provide a protein product that is enriched for bioactive protein, as compared to the levels of bioactive protein in a corresponding protein product made from whey, and wherein the bioactive protein comprises lactoferrin, lactoperoxidase, albumin, a growth factor or an immunoglobulin. Applicants are also claiming a product prepared by the process of claim 1, and a human nutritional product comprising a protein product manufactured according to the process of claim 1, wherein the product is

selected from the group consisting of an infant formula, an adult nutritional product, a medical nutritional formula, a nutritional supplement product, and a nutritional food.

*A. The Rejection under 35 U.S.C. §102*

The Examiner's rationale for the rejection under §102(b) appears to be on the basis of anticipation by inherency. As in the previous Office Action, in the Final Office Action, the Examiner states that "[t]he claims appear to differ as to the recitation of specific bioactive proteins" and "[t]he bioactive proteins are inherent to that of Wu [U.S. Pub. No. 2002/0044998] as the same components and process steps are used." See Office Action, page 2, paragraphs 5 and 6. Applicants respectfully disagree with the Examiner's assertions. Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration either explicitly or by inherency. *In re Dillon*, 919 F.2d 688, 16 USPQ 2d 1897, 1908 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991)(emphasis added). For the reasons provided hereinbelow, Applicants respectfully assert that the Examiner has not established a *prima facie* case of anticipation or anticipation by inherency.

The Wu publication discloses methods for making an  $\alpha$ -lactalbumin enriched whey protein product by treating whey with an acid to lower the pH of the whey to 4.0 or lower, releasing calcium from the  $\alpha$ -lactalbumin molecule, and precipitating the  $\alpha$ -lactalbumin proteins in the acidified whey solution. Wu also discloses the  $\alpha$ -lactalbumin enriched whey protein product produced by thus method.

Wu does not disclose methods for preparing an enriched bioactive protein product from salt whey wherein fat is removed from salt whey to provide clarified salt whey, and salt is removed from the clarified salt whey to provide a protein product that is enriched for bioactive protein, as compared to the levels of bioactive protein in a corresponding protein product made from whey, and wherein the bioactive protein comprises lactoferrin, lactoperoxidase, albumin, a growth factor or an immunoglobulin. Wu also does not disclose a human nutritional product comprising a protein product manufactured according to the method of Applicants' claim 1, wherein the product is selected from the group consisting of an infant formula, an adult nutritional product, a medical nutritional formula, a nutritional supplement product, and a nutritional food.

Because Wu does not disclose each and every element of claims 1, 3-14 and 22 of the presently pending application, Wu does not anticipate claims 1, 3-14 and 22 of the presently pending application.

Applicants further assert that the Examiner has not established a *prima facie* case of anticipation by inherency. The Examiner is again respectfully reminded that "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." M.P.E.P §2112 (emphasis in original). For the reasons provided hereinbelow, Applicants respectfully assert that the Examiner has not established a *prima facie* case of anticipation by inherency.

The Examiner's continued assertion that the same components are used is erroneous. In the Amendment and Response submitted by Applicants on November 29, 2007, which is incorporated herein by reference, it was pointed out, through a detailed analysis of definitions of "whey" and "salt whey" provided in the present specification and in the art, and applied to the present application, that the starting material of the present application (salt whey) is distinct from the starting material in the Wu publication. Applicants believe that the previously submitted arguments are sufficient to overcome the rejection. However, in an effort to further advance prosecution of this matter, excerpts from the previous response and additional remarks are presented herein.

In the Final Office Action, the Examiner states "Wu teaches whey from cheese-making (0017-0019) which encompasses salt whey as claimed." See Final Office Action, page 3, para.

1. Wu contains no disclosure of "salt whey" whatsoever. Instead, Wu defines "whey from cheese making" as either "sweet whey" or "acid whey." Wu states:

[w]hey is typically obtained during the cheese making or casein process as a result of whey separation and clarification from casein. The whey produced from cheese making is generally referred to as "sweet whey" while whey from cottage cheese sources and acid casein is referred to as "acid whey."

Wu at [0019].

Wu does not state that "salt whey" is part of either "acid whey" or "sweet whey," and the Examiner has not provided any basis in fact or technical reasoning to support the assertion that the whey described and used in Wu encompasses "salt whey."

Moreover, Applicants have previously supplied ample evidence that one of ordinary skill in the art would recognize salt whey to be different than whey. Applicants call the attention of the Examiner to the two articles submitted with the Amendment and Response, submitted November 29, 2007, which evidence that the art worker recognizes "whey" and "salt whey" as two distinct and different by-products of the dairy industry.

Thus, the presently claimed process (claims 1, and 3-13), the product by process (claim 14) and the human nutritional product (claim 22) employ a different starting component than that disclosed in the process of the Wu publication.

Even assuming, *arguendo*, that Applicants method employs the same starting material as that used in the Wu publication, Applicants' claims 1, 3-14 and 22 are still patentable over the Wu publication because Applicants' claims recite a different process and a different product than those disclosed in the Wu publication.

Applicants claims recite a different process than that disclosed in the Wu publication. The process steps provided in Applicants' claim 1, as presently amended, recite: a) removing fat from salt whey to provide clarified salt whey and b) removing salt from the clarified salt whey to provide a protein product that is enriched for bioactive protein, as compared to the levels of bioactive protein in a corresponding protein product made from whey, wherein the bioactive protein comprises lactoferrin, lactoperoxidase, albumin, a growth factor or an immunoglobulin.

In contrast, the process steps disclosed in the Wu publication are 1) lowering the pH of the whey protein product to 4.0 or below and 2) fractionating the proteins in the acidified whey protein product to produce an  $\alpha$ -lactalbumin enriched whey protein product. (See Wu publication, claim 1)

The Wu publication does not disclose a method that recites the steps of removing fat from salt whey to provide clarified salt whey and removing salt from the clarified salt whey to provide a protein product that is enriched for bioactive protein, as compared to the levels of bioactive protein in a corresponding protein product made from whey, wherein the bioactive protein comprises lactoferrin, lactoperoxidase, albumin, a growth factor or an immunoglobulin.

In fact, nothing in the Wu publication suggests the purposeful removal of fat from whey, let alone from salt whey. Instead, Wu emphasizes the necessity of lowering the pH of the whey to 4.0 or lower. Thus, the presently claimed process (claims 1, 3-13), the product by process (claim 14), and the human nutritional product (claim 22) employ different process steps than those disclosed in the Wu publication.

Finally, the product of the Wu publication is different than the product of the presently pending claims. The resulting product of Applicants' process is a protein product that is enriched for bioactive protein, as compared to the levels of bioactive protein in a corresponding protein product made from whey, wherein the bioactive protein comprises lactoferrin, lactoperoxidase, albumin, a growth factor or an immunoglobulin. The Wu publication does not disclose the presence of lactoferrin, lactoperoxidase, albumin, a growth factor or an immunoglobulin in the protein products of Wu. One of skill in the art would readily appreciate that the  $\alpha$ -lactalbumin enriched whey protein product of the Wu publication is not the same as a protein product that is enriched for bioactive protein, as compared to the levels of bioactive protein in a corresponding protein product made from whey, wherein the bioactive protein comprises lactoferrin, lactoperoxidase, albumin, a growth factor or an immunoglobulin.

In sum, Applicants' starting material, process, and products are different than the material, process, and products disclosed in the Wu publication. Therefore, Applicants respectfully assert that the Examiner has not established a *prima facie* case of anticipation or anticipation by inherency, and that the instant application complies with 35 U.S.C. ' 102. Accordingly, withdrawal of the rejection under 35 U.S.C. ' 102 is proper and is respectfully requested.

*B. The Rejection under 35 U.S.C. §103(a)*

Applicants assert that the Examiner has not established a *prima facie* case of obviousness. The factual inquiries for the determination of obviousness, as set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), are as follows:

- 1) determine the scope and contents of the prior art;
- 2) ascertain the differences between the prior art and the claims at issue;
- 3) resolve the level of ordinary skill in the pertinent art; and

4) evaluate the evidence of secondary considerations.

Id. See also M.P.E.P. §2141; KSR v. Teleflex, U.S. Supreme Court, No. 04-1350 (April 30, 2007) (slip opinion). Applicants respectfully assert that the Examiner has not met the requirements for establishing a *prima facie* case of obviousness for the rejection of claims 1, 3-14 and 22.

The entirety of the Wu publication teaches the art worker to prepare an  $\alpha$ -lactalbumin enriched whey protein product from sweet whey, acid whey or "whey protein product." There is no disclosure in the Wu publication of salt whey whatsoever. As discussed above, one of ordinary skill in the art of cheese production would readily appreciate and recognize the differences between salt whey and whey. Thus, it would not be logical for one of ordinary skill in the dairy and cheese making arts to attempt to prepare a protein product from salt whey with the expectation that it would be enriched for bioactive protein, wherein the bioactive protein comprises lactoferrin, lactoperoxidase, albumin, a growth factor or an immunoglobulin, in view of art relating to a different process applied to whey and producing a  $\alpha$ -lactalbumin enriched whey protein product.

Additionally, the Wu publication discloses a process that requires lowering the pH of the whey to 4.0 or lower. The Wu publication would lead the art worker to attempt to prepare a protein product by lowering the pH of whey to 4.0 or lower. The Wu publication simply does not teach or disclose preparing a protein product that is enriched for bioactive protein via the process steps of the present claims: 1) the removal of fat from the salt whey to provide clarified salt whey, then 2) removing salt from the clarified salt whey to provide a protein product that is enriched for bioactive protein, as compared to the levels of bioactive protein in a corresponding protein product made from whey, wherein the bioactive protein comprises lactoferrin, lactoperoxidase, albumin, a growth factor or an immunoglobulin.

There is no logical reason for one of ordinary skill in the art who is interested in preparing an enriched bioactive protein product from salt whey would look to the Wu publication for guidance. In sum, the Wu publication does not render claims 1, 3-14 and 22 obvious, and Applicants respectfully request that the rejection of the claims under 35 U.S.C. §103(a) be withdrawn.

**CONCLUSION**

Applicants respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney (612) 349-9580 to facilitate prosecution of this application.

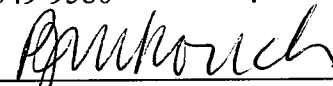
If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date July 29, 2008

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**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 29<sup>th</sup> day of July 2008.

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Name

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